No. 16-1216

In the United States Court of Appeals for the Federal Circuit

PROFOOT, INC.,

Plaintiff-Appellant,

v.

MERCK & CO., INC.,

Defendant-Appellee.

Appeal from the United District Court for the Northern District of Illinois, Case No. 1:11-cv-09004. The Honorable **John Z. Lee**, Judge Presiding.

BRIEF OF PLAINTIFF-APPELLANT

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February 19, 2016

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ProFoot, Inc. v. Merck & Co., Inc.

No. 16-1216

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant ProFoot, Inc. certifies the following:

1. The full name of every party or amicus represented by the undersigned attorneys is:

ProFoot, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by the undersigned attorneys is:

ProFoot, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by the undersigned attorneys are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by the undersigned attorneys in the trial court or agency or are expected to appear in this court are:

Niro Law Group, LLC, William L. Niro, Christopher W. Niro Niro Haller & Niro, Inc., Vasilios Dossas

Date: 2/19/2016

<u>/s/ William L. Niro</u>

William L. Niro Attorneys for Plaintiff-Appellant NIRO LAW GROUP, LLC

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STATEMENT OF RELATED CASES

There have been no previous appeals in this case and the Plaintiff-Appellant is not aware of any other case which will directly affect or be directly affected by this Court's decision.

STATEMENT OF JURISDICTION

The District Court had jurisdiction pursuant to 28 U.S.C. § 1338. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1291 & 1295.

STATEMENT OF THE ISSUES

Whether the District Court erred in its construction of two claim terms by importing unnecessary limitations into the claims and adopting claim constructions that are not supported by the intrinsic record.

STATEMENT OF THE CASE

The present appeal stems from the District Court's construction of two claim terms in Plaintiff's method patent, which formed the basis of Plaintiff's underlying infringement suit against Defendant. *See ProFoot, Inc., v. Merck & Co., Inc.*, No. 11-9004, 2015 WL 3798143 (N.D. Ill. June 17, 2015). Because the court's claim construction ruling is contrary to the ordinary and customary meaning of the claim terms in Plaintiff's patent, the ruling should be vacated as to those terms, the Stipulated Judgment reversed, and the case remanded for further proceedings consistent with this Court's revised claim construction.

A. The Invention

Eric Ward, the inventor of US Patent 6.845,568 at issue in this case, is a ski instructor and foot care specialist trained and educated in providing orthotics designed to place a user's foot in an optimal position for foot function. Based on his observations of human motion and experimentation, he concluded that most individuals could perform better if their bodies were in an aligned, balanced state when in motion. To simulate that state of human motion, Mr. Ward experimented with various methods of analysis and concluded that dynamic balance could be best determined by observing a person when standing on one foot. (Appx524-526). When walking, a person is, in reality, balancing on one foot—exchanging that onefooted balance from the right to left foot repetitively. As a ski instructor, he noticed that in skiing, as it is in many sports, a person's weight is shifted from one foot to the other. Imbalance caused by the foot's specific characteristics, Mr. Ward observed, directly impacts performance.

Observing and then measuring imbalance became the focus of Ward's efforts to develop a method to adjust a person's foot to account for the degree of pronation or supination that placed the individual out of alignment and balance. (*See* Ex.3, Appx511; Ex.11, Appx519; Exs. 12-14, Appx520– 523; and Ex. 17, Appx527). In pronation, the human foot rolls inward and alters the alignment of the knee and lower leg. In supination, the foot rolls outward and likewise, alters

the person's alignment and balance. A variety of corrective devices can be used to adjust the pronation or supination of an individual's foot to achieve what is known by persons of skill in the art as an anatomically neutral position.

In September 2000, Mr. Ward first applied for a patent on his apparatus developed to measure and correct for imbalance. Using those measurements, he then molded a custom fit insole from a blank using a series of jigs and leveling devices. (Appx 74-84). Some of the devices identified by Mr. Ward facilitated the grinding and shaping of the bottom of the custom-made insole into an angular wedge. That angular shaping corrected the pronation or supination to place the wearer in a balanced, neutral state. On May 20, 2003, the application issued as U.S. Pat. No. 6,564,465 ("the '465 Patent") with a claim that covered only a system for creating a custom made foot bed insert.

On May 14, 2003, Ward filed his Continuation-in-Part Application (Appx 169- Appx 229), claiming the method of fitting an individual with pre-made foot inserts that is at issue in this case. That CIP Application issued as method patent no. 6,845,568 on January 25, 2005 ("the '568 Patent"). The '568 Patent claims a method for measuring the pronation or supination of an individual's foot in a manner designed to achieve the optimal foot function when in motion. (Appx 39-Appx 45).

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Plaintiff's description of a person of skill in the art was undisputed in the Claim Construction proceedings:

a person having ordinary skill in the art is a person with education, experience, knowledge and skill in biomechanics, sports specific athletic training, anatomy, kinesiology, dynamic body movement, balance, foot movement, pressure points, foot pressure vis-a-vis dynamic balance all in conjunction with human movement, footwear and/or foot orthotics. Eric Ward is a person of skill in the art of the patented method.

(Appx 260).

B. Mr. Ward Sought to Commercialize His Invention

In 2003, Mr. Ward approached Schering-Plough, the predecessor to Defendant Merck, in the hopes of commercializing his invention in the mass retail market. Mr. Ward's counsel presented his first patent application to Ms. Nancy Miller-Rich at Schering-Plough, and advised her that Mr. Ward was continuing to develop his invention and had applied for additional patent protection. Shortly thereafter, Schering-Plough notified Mr. Ward that it was not interested in pursuing a relationship based on his patented invention. (Appx 233-34).

C. Defendant Enters The Market And Infringes The Ward '568 Patent

Although Schering-Plough was well aware of Mr. Ward's patents (Appx234), it began to test market its Dr. Scholl's Custom Fit Orthotics Kiosks in a number of major retail stores. In or about late 2010, it implemented a nationwide

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launch of the Kiosks selling its line of Dr. Scholl's Custom Fit Orthotics. (Appx 234).

The Kiosks infringed on Mr. Ward's patent, utilizing his patented method, by (1) instructing a customer to stand on a measuring device, while elevating one foot off of the device; (2) using the measurements to determine the position necessary to place the individual in a balanced, neutral position; (3) repeating the measuring process for the right foot; and (4) providing a recommended orthotic from a selection of premade inserts. (Appx 234-35).

In 2011, shortly after learning of the Kiosks, Mr. Ward again contacted Ms. Miller-Rich, the Group Vice President, Global New Ventures & Strategic Commercial Development at Merck, informing her of the '568 Patent, (Appx 234), and notifying her that Merck's method for measuring and recommending a custom orthotic from a plurality of premade inserts infringed the '568 Patent. (*Id.*).

Defendant continues to make, distribute, market, and sell Dr. Scholl's custom fit orthotic products, including the Kiosks. (*Id.*).

D. Procedural History

On December 20, 2011, Mr. Ward filed suit against Walgreen Company and Sears Holdings Corporation for infringement of the '568 Patent in connection with the sale of Dr. Scholl's brand Custom Fit Orthotics. (Appx 27). In February 2013, Mr. Ward filed his Second Amended Complaint against Merck & Co., Inc., and

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voluntarily dismissed Walgreen Company and Sears from the case. (Appx 28). In January 2014, Mr. Ward sold all right, title and interest, including the right to sue for past, present and future infringement, in the '568 Patent to ProFoot, Inc. ProFoot then filed, on January 31, 2014, its Third Amended Complaint in its name against Merck & Co, Inc., and terminated Eric Ward as a party to the action. (Appx 29).

On June 27, 2014, the District Court held a *Markman* hearing pursuant to Local Patent Rule 4.3 to construe the claim terms of the '568 Patent. (Appx 416-Appx 505). Presentation of argument on the patent claim terms was preceded by a tutorial presented by counsel for the parties. (Appx 416- Appx 449). The District Court did not ask for expert testimony, although Defendant objected to Plaintiff's request to have the inventor Eric Ward provide testimony during the tutorial phase of the presentation. The Court sustained the objection and Mr. Ward was not permitted to present any evidence or inform the Court in connection with the patent claims. (Appx 420). Plaintiff's tutorial focused on the human foot, human anatomy (Appx 421 and Exs. 1, 2 & 3, Appx 509, Appx 510 and Appx 511) and the range of shoe inserts available on the market—from accommodative foam shoe interests (Exs. 4 & 5, Appx 512- Appx 513) and the accused Dr. Scholl's products (Ex. 8, Appx 516), to custom made corrective inserts produced by Mr. Ward (Appx 514-515), and the plurality of predetermined inserts identified in claim 3 of Mr.

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Ward's method patent (Exs. 9 & 10, Appx 517- Appx 518). After the tutorial, each side presented their arguments on the meaning of the disputed claims of the Ward '568 method patent. (Appx 449- Appx 505).

Mr. Ward used the term "neutralizer" to claim a device that is capable of measuring the degree of correction needed to place a user's foot in a "neutral position." Plaintiff contends that Mr. Ward did not limit the claims of his method patent to a measuring device with particularly defined components. (Appx 502-Appx 503).

On June 17, 2015 the District Court issued its Memorandum Opinion and Order construing the claims of the Ward '568 method patent. (Appx 2- Appx 18). The District Court limited the term "neutralizer" to a single embodiment of a "measuring device" to construe the word "neutralizer" to mean "a device that includes a housing, a protractor, and an angularly adjustable plate capable of supporting the foot." (Appx 10). That specific embodiment is not claimed in Mr. Ward's '568 *method* patent. In making that determination the District Court adopted the language of the claim stated in the '465 *apparatus* patent. (Appx84, Col.5 Il. 5-6).

The District Court's construction also limited the term "neutral position." Plaintiff contended that the term should be given its plain and ordinary meaning. (Appx 411). To a person skilled in the art, the term "neutral position" does not

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require further construction. If further definition is required, "neutral position" simply means the "optimal position for foot function," or in a "balanced position." Ward was aware of that definition. Indeed, he cited the Waters patent (Appx593-602), which expressly defines "neutral position" as "optimal position, for foot function." (Appx598, Col. 1, Il.13-16).

Defendant's proposed construction sought to import limitations into an ordinarily understandable term. (*See* Appx 411) ("A state or position in which the tendons by the individual's ankle are in a relaxed state or are working equally."). Ward's patent specification refers to observation of tendons by the ankle as an example of one way of determining relaxed state, but his claims are in no way limited to measurement by observing the subtalar joint. (Appx 44, Col. 4, Il. 21-28). Further, he does not define the "neutral position" by reference to achieving "a lack of pronation or supination." The District Court eschewed both positions, holding that "neutral position" means "a position in which subtalar joint is in the relaxed position due to the lack of pronation or supination." (Appx 12).

Based on the claim construction, the parties stipulated to a Final Judgment of Non-Infringement. (Appx 19- Appx 21). The District Court entered Final Judgment in accord with the Stipulation. (Appx 22). Plaintiff timely appealed to this Court on October 23, 2015. (Appx 38).

SUMMARY OF THE ARGUMENT

The Court should vacate the District Court's claim construction ruling as to the terms "neutralizer" and "neutral position," and apply the plain and ordinary meaning of those terms without further construction. It should thereafter remand this matter for proceedings consistent with its revised claim construction. If the Court concludes that further definition of the terms is required, the Court should construe: (1) "neutralizer" as "a device that is capable of determining the neutral position," or more specifically "a device that measures the degree of pronation or supination of a foot in order to determine the neutral position of that foot"; and (2) "neutral position" as the "optimal position for foot function" or "balanced position." These constructions accurately describe the claim terms at issue as understood by persons of ordinary skill in the art.

The District Court's construction of the term "neutralizer" erroneously confined the embodiment described in the patent to the exclusion of all other possible embodiments. This Court has repeatedly warned against unnecessarily cabining claims to narrow patents, and has expressly rejected the notion that if a patent describes a single embodiment, then the patent must be construed as only reflecting *that* embodiment. The '568 Patent expressly contemplates use of other embodiments to perform the patented *method*. The District Court lost sight of the fact that the purpose of the specification is to teach and enable those of skill in the

art to make and use the invention, and preferred embodiments are merely meant to provide a best mode for doing so.

Similarly, the District Court's construction of the term "neutral position" failed to apply the plain and ordinary meaning as understood by one skilled in the art. "Neutral" is a term of art employed throughout the '568 Patent, and a term used by other inventors whose patents were cited by the Examiner. Plaintiff submits the term requires no further construction beyond its ordinary meaning. If the term does, in fact, require further definition, "neutral position" means quite simply, "optimal position for foot function." By adopting an imprecise and confusing construction, the District Court failed to give this term its plain and ordinary meaning as understood by those skilled in the art.

ARGUMENT

I. STANDARD OF REVIEW

Because the court did not resolve subsidiary factual matters in the course of patent claim construction, the District Court's claim construction ruling is reviewed by this Court *de novo*. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 834 (2015) ("When the district court reviews only evidence intrinsic to the patent, the judge's determination is solely a determination of law, and the court of appeals will review that construction *de novo*.").

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II. THE COURT ERRED IN ITS CONSTRUCTION OF THE CLAIM TERM "NEUTRALIZER"

The patent-in-suit is directed to those skilled in the art. The proper focus must be what a person of ordinary skill in the art knows and understands at the time of the invention. Persons of skill in the art are knowledgeable of various devices and methods for measuring body motion and certain anatomical aspects of the human foot. (Appx 603- Appx 609). The '568 Patent's claims recite a method for determining the degree of supination and pronation of the foot, by analyzing each foot individually, such that a corrective insert can be prescribed to place the wearer in a balanced, neutral position. A person of ordinary skill in the art would understand this method in light of the cited references as requiring measurement using some sort of balance analyzer. Ward clearly identifies the use of a "balance analyzer," and chose to use "neutralizer" as the term for that analyzer. (Appx 43, col. 2 ln. 19). It is clear that a neutralizer is simply a device for analyzing and measuring in order to place a user's foot in a "neutral position."

Nowhere in the claims does the method patent describe the neutralizer as requiring a housing, protractor, or angularly adjustable plate. Claim 1 requires only to "... place the right foot on a neutralizer... using the neutralizer *to determine the angle* necessary to place the right ankle in a neutral position." (Appx 45, col. 5 ll. 11-15). The specification clearly states that a device "such as" *a neutralizer* is required (Appx44, col. 3, ll.1-2), not that a certain *type* of neutralizer

is required. The emphasis throughout the patent is on the need to obtain a measurement for achieving a neutral position of an individual foot.

The language in the court's construction suggests that a person of skill in the art would understand a neutralizer to mean a particular device requiring three specific characteristics. (Appx 7- Appx 8). The court's conclusion comes from the specification's description of one such measuring device, which came from Mr. Ward's claims in the parent '465 apparatus patent. (*Id.*) The District Court's unduly narrow construction is improper and should be vacated. In the '568 method patent, a "neutralizer" is properly construed as "a device that is capable of determining the neutral position" or "a device that measures the degree of pronation or supination of a foot in order to determine the neutral position of that foot." This construction is supported by the intrinsic record and based on the plain and ordinary meaning of the term as understood by a person of ordinary skill in the art.

A. The Court's Construction Improperly Imported Limitations From The Specification Of The Apparatus Patent Into the Claims Of The Method Patent

The patent specification is always relevant to the claim construction analysis and "[a]part from the claim language itself, the specification is the single best guide to the meaning of a claim term." *Vederi, LLC v. Google, Inc.*, 744 F.3d 1376, 1382 (Fed. Cir. 2014) (internal quotations omitted). This analysis must be done,

however, through the eyes of a person of ordinary skill in the art. *Id.* Importantly, inventors are free to choose a broad term and expect protection for the full scope of its ordinary meaning unless they explicitly narrow it. *See Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). Courts must cautiously look to the specification for assistance in defining unclear terms, but not to limit clear terms. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-1187 (Fed. Cir. 1998). Further, it is improper to rewrite the claims, either by disregarding words that are present or adding others that are not. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 (Fed. Cir. 1987).

The '568 Patent describes a method for analyzing the foot to achieve a neutral, balanced position. In order to practice this method, a measuring device of some sort is necessarily required – Ward chose to name his device a neutralizer, or balance analyzer. (Appx 44). That term has no inherent structural limitation. The balance analyzer featured in the specification is but one embodiment that could be used to determine the balanced position of a foot. Limiting the claim term "neutralizer" to that one embodiment is improper. This Court has often held that importing limitations from a preferred embodiment into the claims of the patent is impermissible, yet that is precisely what the District Court erroneously did below. See, e.g., Beckson Marine v. Nfm, Inc., 292 F.3d 718, 723 (Fed Cir. 2002) ("[T]he district court improperly narrowed the scope of claim 1 by importing limitations

from the specification") (emphasis added); *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998) ("[A] court may not import limitations from the written description into the claims.").

It is a critical and fundamental principle of claim construction that a court interpret the terms of the patent in line with how a person having ordinary skill in the art would interpret the terms. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005) ("The underlying goal of our decision in *Vitronics* was to increase the likelihood that a court will comprehend how a person of ordinary skill in the art would understand the claim terms."). Here, the District Court gave no indication of who it considered to be a person of skill in the art despite Plaintiff's request that it do so. It then construed the term in a manner that does not reflect what the person of ordinary skill would know at the time of the invention.

One cited prior art reference, U.S. Patent No. 5,979,067 issued to Waters ("Waters '067"), serves as a good example of what a person of skill in the art knew and understood at the time of the invention about human anatomy and various ways to determine foot posture. (Appx 93). Waters evaluates foot posture and its effect on the functional dynamics of a person's lower extremities. Waters' '067 patent claims specific "measuring devices" for analyzing foot posture. (Appx 600-Appx 603). The Ward '568 method patent is distinguishable from Waters '067 because Ward's method requires that a measuring device be used, one foot at a

43). When reading the Ward patent as a whole, a person of skill in the art would understand that the method disclosed is intended to create inserts that improve balance. In other words, a person of skill in the art would understand that a neutralizer is a measuring device—a tool used to measure a foot's position in an optimal, balanced state, *i.e.*, a "neutral position."

Here, Mr. Ward did not limit the scope of the claims to one specific measuring device, but the specification instead described a type of device which *could* be used to practice the patented method. A neutralizer containing a housing, protractor, and an angularly adjustable plate, as claimed in the '465 apparatus patent, is simply but one embodiment of a device which could be used to measure the correction needed to put the foot in a balanced or neutral position.

A person of skill in the art, for example, would be well aware of multiple devices capable of analyzing foot posture, and would not limit this method to one specific device having specific structural elements. Accordingly, this Court should reverse the District Court's improperly narrow construction of "neutralizer" and adopt the plain and ordinary meaning of the term, which Plaintiff submits is "a device that is capable of determining the neutral position" or "a device that measures the degree of pronation or supination of a foot in order to determine the neutral position of that foot."

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B. The Ward '568 Patent Specification Did Not Clearly Disavow Any Other Measuring Devices Which May Be Used With This Method

The District Court's conclusion that "all embodiments of a 'neutralizer' have these structural elements" is simply incorrect. (Appx 8). Waters' '067 patent describes several neutralizers that do not contain the structural elements noted in the Ward '568 Patent. In fact, Waters' '067 "neutralizer" (measuring device) does not feature any of the structural elements identified by the District Court. The District Court's Opinion appears to conclude that Mr. Ward disavowed all other measuring devices. The District Court's conclusion is not supported by the intrinsic record and this Court's precedent.

Absent a clear disavowal, the patentee is entitled to a "strong presumption" that the claims must be given their plain and ordinary meaning as depicted in the claim itself. *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1371 (Fed. Cir. 2003). A party seeking to limit a claim term based on a patent's specification must meet a "stringent" and "exacting" standard – indeed, such limitations are only appropriate where (1) the patentee acted as its own lexicographer, clearly setting forth a definition other than the plain and ordinary meaning of a term; or (2) the patentee clearly disavowed the full scope of a claim term. *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012). To act as its own lexicographer, a patentee must "clearly set forth a definition of the disputed claim term," and "clearly express an intent to define the term." *Id.*

Even using the phrase "the present invention" or describing only one example will not limit the claims to the disclosed embodiment unless accompanied by additional language of express limitation. Compare Thorner, 669 F.3d at 1366 (finding broad claims despite "present invention"), and Liebel-Flarsheim v. Medrad, Inc., 358 F.3d 898, 905 (Fed. Cir. 2004) (finding broad claims despite one example), with SciMed Life Sys., Inc. v. Adv. Cardiovascular Sys., Inc., 242 F.3d 1337 (Fed. Cir. 2001) (finding "present invention" plus explicitly disparaging prior art embodiments and expressly disclaiming alternative embodiments collectively amounts to disavowal). Here, Mr. Ward never explicitly or implicitly disavowed or limited his invention to one embodiment. Specifically, in describing his invention Ward stated that the present invention includes components "such as" a foot neutralizer, leaving no dispute that other devices were contemplated, or well understood to exist by those skilled in the art. (Appx 44, col. 3 ll. 1-2).

Recently, this Court in *Openwave Sys. v. Apple, Inc.*, 808 F.3d 509 (Fed. Cir. 2015), analyzed the issue of disavowal in depth. There, this Court, in affirming the district court's construction, relied upon passages in the specification that disparaged the prior art implementation of a "computer module on a mobile device," and found that the derogatory statements reasonably may be viewed as a disavowal of that subject matter from the scope of the claims. *Id.* at 514. Further, the Court noted that the specification defined problems with the prior art that the

present invention purported to solve, which amounted to a disavowal of the subject matter in the prior art, not included in the present invention. *Id.* at 515. Here, Mr. Ward never disparaged prior art implementations to suggest disavowal and limitation to one specific structural embodiment.

Absent a clear and express disparagement as found in *Openwave*, to find disavowal, the Court must find that the specification is "both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer." Dealertrack, Inc. v. Huber, 674 F.3d 1315, 1322 (Fed. Cir. 2012) (internal quotation marks omitted). To find disavowal of a particular feature, the Court must analyze whether the specification goes beyond expressing the patentee's preference such that repeated derogatory statements about a certain feature reasonably may be viewed as a disavowal. Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC., 677 F.3d 1361, 1372 (Fed. Cir. 2012); see also SafeTCare Mfg., Inc. v. Tele–Made, Inc., 497 F.3d 1262, 1269–70 (Fed. Cir. 2007) (finding disclaimer where the specification repeatedly indicated that the invention operated by "pushing (as opposed to pulling) forces," and then characterized the "pushing forces" as "an important feature of the present invention").

Moreover, this Court has recognized that even when the specification states that a certain element was advantageous over prior designs, it is improper to import a function from the specification into the claim. *See Toro Co. v. White*

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Consolidated Industries, 383 F.3d 1326, 1330 (Fed. Cir. 2004) (overturning a narrow construction of a claim term even when the specification praised the advantages to the present invention over the prior art). Here, Mr. Ward did not disclaim any features to limit his invention to the narrow construction adopted by the District Court.

The intrinsic record does not support a conclusion that Mr. Ward disavowed embodiments not containing a housing, protractor, and angularly adjustable plate by praising the present invention or disparaging the prior art. This Court should overturn the District Court's construction and construe "neutralizer" to mean "a device that is capable of determining the neutral position" or "a device that measures the degree of pronation or supination of a foot in order to determine the neutral position of that foot."

C. The Court Improperly Limited The Claim Term "Neutralizer" To One Preferred Embodiment

This Court has consistently held that that even if a patent's specification describes only a single embodiment, the claims are not to be confined to that embodiment. *See, e.g., Nazomi Communications, Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1369 (Fed. Cir. 2005) (claims may embrace "different subject matter than is illustrated in the specific embodiments in the specification."); *Gemstar-TV Guide v. Int'l Trade Comm.*, 383 F.3d 1352, 1366 (Fed. Cir. 2004) ("Our precedent has emphasized that the disclosure in the written description of a single

embodiment does not limit the claimed invention to the features described in the disclosed embodiment") (citing *Liebel-Flarsheim* 358 F.3d at 906 ("This court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.")); *Va. Panel Corp. v. MAC Panel Corp.*, 133 F.3d 860, 866 (Fed. Cir. 1997) ("Device claims are not limited to devices which operate precisely as the embodiments described in detail in the patent.") The District Court's construction limits the claim term "neutralizer" to one preferred embodiment, given as an example in the specification, of a measuring device one could use to practice this method. (Appx9).

Claims may embrace "different subject matter than is illustrated in the specific embodiments in the specification." *Liebel–Flarsheim*, 358 F.3d at 906–08. Section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant and persons of ordinary skill in the art would rarely confine their definitions of terms to the exact representations depicted in the embodiments. *Id*.

The District Court incorrectly construed "neutralizer" to include three specific structural embodiments, including "a housing, an angularly adjustable plate capable of supporting the foot, and a protractor." (Appx7) This is but one preferred embodiment of a balance analyzer or neutralizer. The District Court's

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opinion goes on to note that "all embodiments of a 'neutralizer' have these structural elements." (Appx 8). However, the District Court only cited to the preferred embodiment in the '568 Patent in support of its construction, and adopted the exact language of the claim of the '465 apparatus patent to construe the claim. (Appx 8). Even if the preferred embodiments of the Ward '568 Patent are the only places where a claim term is used, it is still improper to import exclusively those embodiments into the claim. *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 805 (Fed. Cir. 2007) (finding that Stryker's "assertion is flawed: it is an attempt to import a feature from a preferred embodiment into the claims."). Using the preferred embodiments as "support" for the court's construction narrows the claim more than is allowed under the plain and ordinary meaning to a person of skill in the art.

Although the elements of the embodiment are described more than once in the specification, this Court should not limit the *method* patent to requiring one particular balance analyzer, but instead any device used to analyze pronation or supination of a foot.

Mr. Ward used expansive language to describe the preferred embodiments of the '568 patent. In *IP Innovation, L.L.C. v. eCollege.com*, 156 F. App'x 317, 321-22 (Fed. Cir. 2005), the patentee used the word "embodiment" to refer to non-inventive features and limited its invention to its specific embodiments. This Court

noted that the patentee should have used language such as "in the present embodiment' or 'in one embodiment," and failure to do so could not be overcome with boilerplate language. *Id.* Such expansive language is present in several sections of the specification of the '568 Patent:

"Fig 1. Shows a perspective view of *one embodiment* of a foot neutralizer used with the present invention." (Appx 43, col. 2, ll. 36-37).

"The present invention includes a number of components *such as* a neutralizer." (Appx 44, col. 3, ll. 1-2).

"Fig. 2 shows *an alternate embodiment* of a foot neutralizer 100." Id., col. 3, ll. 10-11.

Mr. Ward therefore clearly stated that Fig 1 was "one embodiment," Fig 2 showed "an alternate embodiment," and in describing the present invention, used the words "such as a neutralizer." Additionally, Mr. Ward also referred to the "neutralizer" as a "balance analyzer" in the summary of the invention. (Appx 43., col. 2 l. 19). These phrases and word choices throughout the patent are indicative of Mr. Ward's clear intent to include various balance analyzing devices to perform the patented method, so long as the balance analyzer or neutralizer is capable of determining the angle necessary to place the foot in a neutral position. A person of skill in the art would clearly understand that intent.

Thus, upon *de novo* review, this Court should consider the scope of the patent as a whole, the expansive language used, and the total lack of disavowal of alternate designs in the specification to conclude that a "neutralizer" as used in this patent means, to a person of skill in the art, "a device that is capable of determining the neutral position" or "a device that measures the degree of pronation or supination of a foot in order to determine the neutral position of that foot."

D. The Court Improperly Relied On The Parent Patent's Prosecution History To Unduly Narrow The Claim Term

The District Court improperly cited the prosecution history of the *parent* '465 patent as supporting its narrow construction. (Appx 8). The prosecution history of a patent is accorded the least weight of all intrinsic evidence when interpreting a claim, but may illustrate how the inventors and the USPTO understood the scope of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). Prosecution history is typically only used to determine how the USPTO and inventor understood the claims and terms to mean by interpreting the differences between language and phrasing at different stages of the prosecution. Because the file history "often lacks the clarity of the specification and thus is less useful for claim construction purpose it is particularly important not to limit claim slope based on statements made during prosecution absent a clear disavowal or contrary definition." Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc., 672 F.3d 1270, 1276 (Fed. Cir. 2012).

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Here, the District Court looked to the prosecution of the *parent* '465 patent in determining the meaning of "neutralizer." The District Court construed that the neutralizer must have a housing, a protractor and an angularly adjustable plate capable of supporting the foot. (Appx10). The court concluded that because the inventor did not indicate that the neutralizer was different in the '568 patent than described in the '465 parent patent, a neutralizer must have a narrow construction. This matter was specifically addressed during the *Markman* hearing:

THE COURT: So I take it that your answer to my question of whether or not Mr. Ward intended neutralizer to have different meaning in the '465 patent versus the '568 patent is yes, he did?

MR. C. NIRO: He intended to have different meanings, that's correct, your Honor. That's Correct.

(Appx502-503). Mr. Ward specifically contemplated including that limiting language in the parent '465 Patent claims, and chose to exclude it from the '568 Patent claims.

The Court concluded that because the Ward '465 parent apparatus patent includes the three limitations in the claim language, Mr. Ward intended to limit his method claim to neutralizers containing these specific elements. There is *no* support for that conclusion in the law or the intrinsic record. There is, however, compelling support for the contrary conclusion: Mr. Ward specifically *omitted* that language from the *method* patent. No evidence supports the conclusion that Mr. Ward "clearly intended one type of neutralizer to be used with this method."

Instead, the prosecution history of the Ward '568 Patent supports the Plaintiff's proposition that a "neutralizer" in the '568 method patent encompasses any type of balance analyzer capable of measuring the degree of pronation or supination of a foot in order to determine the neutral position of that foot.

III. THE COURT ERRED IN ITS CONSTRUCTION OF THE CLAIM TERM "NEUTRAL POSITION"

Claim terms "are generally given their ordinary and customary meaning." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*).

The District Court erred by failing to construe the claim term "neutral position" through the eyes of one skilled in the art. A person skilled in the art would understand that the term "neutral position" has an ordinary and customary meaning, and thus requires no further construction.

"Neutral" is a term of art in foot care that Mr. Ward used throughout the patent. For instance, Mr. Ward repeatedly refers to "neutral position," "neutral state," and "neutral angle." (Appx39-45). If the term requires further definition, however, "neutral position" simply means the "balanced position" or the "optimal position for foot function." Indeed, Mr. Ward's clear objective was to place his

customers' feet in the optimal position for foot function by taking into account dynamic balance. Similarly, the Waters '067 patent expressly defines the "neutral position" as the "optimal position, for foot function." (Appx598, col. 1, ll. 13-16).

The District Court improperly limited the definition of "neutral position," to "a position in which the subtalar joint is in the relaxed position due to the lack of pronation or supination." (Appx10-12). That definition is found nowhere in Ward's method patent claims, and only serves to add confusion to an otherwise clear and understandable term of art.

In reaching its construction, the District Court did not conclude that a person skilled in the art would understand the term "relaxed position" to help define the term "neutral position." The District Court made no reference to any cited prior art. In fact, the term "relaxed position" has no ordinary or common meaning in the art and is more difficult to construe than "neutral position."

Moreover, it is clear that Ward understood "relaxed" and "neutral" to have different meanings because he used both terms in different contexts. *See, e.g.*, *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) ("[W]hen an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms."). Ward uses "relaxed position," "relaxed stance" and "relaxed state" throughout the patent, but he does not use

"relaxed" as synonym of "neutral." For example, Ward uses the term "neutral angle," which could not plausibly be construed to mean "relaxed angle."

The District Court also erred by importing a limitation into the claim that requires reference to the subtalar joint. The specification describes observation of the "tendons by the ankle" not the subtalar joint. The '568 Patent claims do not limit the invention to methods that require observation of the subtalar joint. Ward did not intend to limit his method patent to a single method of observation, and it is improper to import such a significant limitation into his claims.

Finally, the added language "due to the lack of pronation or supination" is also imprecise and inaccurate. Pronation is the inward roll of the foot and the purpose of the patent is to provide an orthotic that achieves optimal pronation, not a "lack of pronation." As the patent teaches, the "optimal outcome should be to limit the amount of pronation in the ankle to approximately two degrees."

(Appx44, col. 4, ll. 21-25). There is thus no basis for construing the term "neutral position" as "due to a lack of pronation." That language is imprecise and prone to cause confusion.

For these reasons, the Court should hold that the term "neutral position" is a common and ordinary term in the art that requires no further construction, or simply should be construed to mean "the optimal position for foot function" or "balanced position."

CONCLUSION

Upon *de novo* review, this Court should adopt a construction of the term "neutralizer" as used in claim 1 of the "568 Patent to include "a device used to determine the neutral position," or more specifically "a device that measures the degree of pronation or supination of a foot in order to determine the neutral position of that foot." This construction is supported by the relevant law with knowledge of a person of ordinary skill in the art. There was no clear disavowal of alternate balance analyzers or measuring devices. The District Court's construction improperly limited the claim term to the preferred embodiment in the specification.

In addition, this Court should hold that "neutral position," as used in claim 1 of the '568 Patent, is a commonly understood term to those skilled in the art that requires no further construction. If further construction is required, "neutral position" means simply the "optimal position for foot function" or "balanced position."

* * *

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For the foregoing reasons, the construction of those terms by the District Court should be vacated, the Order granting the Stipulated Final Judgment of Non-Infringement reversed and this case remanded for further proceedings consistent with this Court's revised claim construction.

Respectfully submitted,

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ADDENDUM

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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

PROFOOT INC.,)
Plaintiff,)) 11 C 9004
,	,)
v.) Judge John Z. Lee
)
MERCK & CO., INC.)
)
Defendant)

MEMORANDUM OPINION AND ORDER

Plaintiff Eric Ward ("Ward") has sued Defendant Merck, Inc. ("Merck") alleging infringement of U.S. Patent No. 6,845,568 (the "'568 Patent"). The allegedly infringing activities concern Dr. Scholl's Custom Fit Orthotic Centers and Custom Fit Orthotic Inserts, which are manufactured, marketed, and sold by Merck. 3d Am. Compl. ¶ 50, 51, 54; Def.'s Resp. 3d Am. Compl. ¶ 12. Merck has placed Dr. Scholl's Custom Fit Orthotic Centers throughout the United States in various retail stores, including Walgreens and Sears. Def.'s Resp. 3d Am. Compl. ¶ 15. The original complaint named only Walgreen Company ("Walgreens") and Sears Holdings Corporation ("Sears") as defendants. Compl. ¶ 5-6. But Ward later amended the complaint to include Merck and then voluntarily dismissed the suits against Walgreens and Sears. 1st Am. Compl. ¶ 5; dkt. 28, 29. Subsequently, ProFoot, Inc. ("ProFoot") purchased the patent-in-suit from Ward, including the right to sue for past, present, and future infringement. 3d Am. Compl. ¶ 2. The parties now ask the Court to construe six terms that appear in the '568 Patent.

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I. Background

The patent-in-suit relates to a method for measuring and correcting the pronation of a person's foot. *See* '568 Patent col.1 ll.17-18, Joint Appendix ("J.A.") 93. The method utilizes a device called a "neutralizer" in the following manner. First, an individual places one foot on the device while keeping another foot off of it. *Id.* at col.5 ll.11-13, col.6 ll.3-5, J.A. 95. Then, the "neutralizer" is used to determine "the angle necessary to place the [right or left] ankle in a neutral position." *Id.* at col.5 ll.14-15, col.6 ll.6-7, J.A. 95. Finally, an individual is provided with "an insert having an angle which represents the neutral state for the [right or left] ankle." *Id.* at col.6 ll.1-2, 8-9, J.A. 95. This method enables the individual to correct any pronation by obtaining a foot insert that may be used in "ski boots, skates, bike shoes and the like." *Id.* at col.1 ll.9-12, J.A. 93.

On September 22, 2000, Ward filed U.S. App. No. 09/667,998, the parent application of the patent-in-suit. It disclosed a system and a method for measuring foot pronation and correcting it by using a foot insert. U.S. App. No. 09/667,998, J.A. 27. On May 20, 2003, the application issued as U.S. Pat. No. 6,564,465 (the "'465 Patent") with a claim that covered only a system for creating a foot insert. '465 Patent, J.A. 11. This patent is not asserted in the present case.

On March 14, 2003, Eric Ward filed U.S. App. No. 10/389,435 as a continuation-in-part of U.S. App. No. 09/667,998. U.S. App. No. 10/389,435, J.A. 96. This second application claimed only a method of fitting an individual with the foot inserts. *Id.* at 113-14. It issued as the '568 Patent—the patent asserted in this case.

To furnish foot inserts to its customers, Merck developed special kiosks, called Dr. Scholl's Custom Fit Orthotic Centers. Def.'s Resp. 3d Am. Compl. ¶ 13. These kiosks, located

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in various retail stores in the United States including Walgreens and Sears, contain a pressure-measuring device. *Id.* ¶¶ 15, 19. This device allows customers to analyze their feet, so that they can use these measurements to choose one of the off-the-shelf Dr. Scholl's Custom Fit Orthotic Inserts. *Id.* ¶¶ 19, 22.

The following terms of the '568 Patent are in dispute: (1) neutralizer; (2) neutral position; (3) using the neutralizer to determine the angle necessary to place the <right or left> ankle in a neutral position; (4) providing an insert having an angle which represents the neutral state for the <right or left> ankle; (5) creating a <right or left> foot insert; and (6) predetermined inserts.

II. <u>Legal Standard</u>

Claim construction is a question of law to be decided by a judge. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). Words "are generally given their ordinary and customary meaning." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). A person of ordinary skill in the art is assumed to read the claim term in the context of the entire patent. *Id.*

The Court's analysis begins with the intrinsic evidence, which consists of the patent itself (including claims, specification, and Abstract) and the prosecution history. *Vitronics*, 90 F.3d at 1582 ("in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history"); *Hill–Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 1341 n.1 (Fed. Cir. 2000) (courts "have frequently looked to the abstract to determine the scope of the invention"). The specification is usually "dispositive; it is the single best guide to the meaning of a disputed

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term." *Vitronics*, 90 F.3d at 1582. Claim terms are given "the meaning and scope with which they are used in the specification and the prosecution history." *Kinik Co. v. ITC*, 362 F.3d 1359, 1365 (Fed. Cir. 2004). But a particular embodiment described in the specification should not be read into the claim when claim language is broader than the embodiment. *Superglide Corp. v. DirecTV Enters.*, Inc., 358 F.3d 870, 875 (Fed. Cir. 2004). That said, a claim may be limited to its preferred embodiment if permitting expansive claim language would undermine the public notice requirements of 35 U.S.C. § 112. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005).

Furthermore, the context in which a term appears in a claim is also instructive. *Phillips*, 415 F.3d at 1314. Likewise, other claims are "valuable sources of enlightenment as to the meaning of a claim term." *Id.* Under the doctrine of claim differentiation, "each claim in a patent is presumptively different in scope." *RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003). "That presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007). Claim differentiation, however, is a "rule of thumb" and not absolute — it does not trump "the clear import of the specification" or the disclaimer of the subject matter in the prosecution history. *See Edwards Lifesciences LLC v. Cook, Inc.*, 582 F.3d 1322, 1332 (Fed. Cir. 2009); *Fantasy Sports Props., Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1116 (Fed. Cir. 2002).

In addition, "the prosecution history can often inform the meaning of the claim language." *Phillips*, 415 F.3d at 1317 (Fed. Cir. 2005). For example, it may be used "as support for the construction already discerned from the claim language and confirmed by the written description." *800 Adept, Inc. v. Murex Sec., Ltd.*, 539 F.3d 1354, 1365 (Fed. Cir. 2008). And

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Courts can consult not only the asserted patent's prosecution history, but also the prosecution history of other patents from the same family. *See Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1375 (Fed. Cir. 2013); *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007). Moreover, the prosecution history may serve to "exclude any interpretation that was disclaimed during prosecution." *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005). However, a claim should not be narrowed "simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

Finally, extrinsic evidence, such as dictionaries and expert testimony, may be used if the intrinsic evidence alone is insufficient to determine the meaning of the claim terms. *Vitronics*, 90 F.3d at 1583.

III. Analysis

A. "Neutralizer"

The parties first disagree on the meaning of the term "neutralizer" used in Claim 1 of the '568 Patent. Merck suggests that "neutralizer" is "a device that includes an angularly adjustable plate and a protractor which are used to measure the angle of adjustment to achieve the neutral position of a specific individual's ankle." Def.'s Reply Br. Claim Construction 1-2 ("Def.'s Reply"). ProFoot argues that this term should be given its plain and ordinary meaning or, if the Court determines that this term needs further construction, that the term be construed as a "balance measuring device." Pl.'s Resp. Claim Construction 5 ("Pl.'s Br.").

The '568 Patent makes it clear that "neutralizer" does not measure all types of balances. The Summary of the Invention explains that there are several types of balances and that the invention deals only with the dynamic one:

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This is the difference between what the present invention achieves and what many others do in this field. All other alignment processes implement a two-footed stance to determine the position of neutrality.... If a person is standing on two feet, ... the person may be maintaining balance equally in all six quadrants or in one of the six quadrants and using two others to maintain a steady or "static" balance.

If you reduce the base of support to only one foot, you have a three-sided base which needs to articulate to maintain balance or balance dynamically. The present invention achieves this state by first analyzing the ankle joint to determine correct foot alignment.

'568 Patent col.2 ll.3-19, J.A. 93. Furthermore, Claim 1 itself provides that "the individual place[s] the right foot on a neutralizer while elevating the left foot off of the neutralizer." *Id.* at col.5 ll.11-13, J.A. 95. Therefore, a "neutralizer" only deals with one-footed "dynamic" balance.

Next, "neutralizer" is not just any "balance measuring device" as ProFoot contends. It has specific functions: to accommodate a single foot and to determine the angle necessary to place the ankle in a neutral position. This is apparent from Claim 1, which covers a method comprising the steps of "having the individual place the right foot on a neutralizer while elevating the left foot off of the neutralizer" and "using the neutralizer to determine the angle necessary to place the right ankle in a neutral position." Id. at col.5 ll.11-15, J.A. 95 (emphasis added). Likewise, the Abstract states that "[t]he neutralizer is adapted to accommodate a single foot of the individual to determine the neutral angle for each foot individually." Id. at Abstract, J.A. 89 (emphasis added). The Description of the Preferred Embodiments also explains that in order "[t]o determine a neutral position, one foot at a time is measured" while "the person stands on [the] foot neutralizer." Id. at col.4 ll.5-9, J.A. 94 (emphasis added).

Finally, the "neutralizer" accomplishes its functions by specific structural elements—a housing, an angularly adjustable plate capable of supporting the foot, and a protractor. Thus, the Abstract of the '568 Patent plainly states that "[t]he neutralizer has a housing, protractor, and an

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angularly adjustable plate capable of supporting the foot." *Id.* at Abstract, J.A. 89. Nothing in the specification contradicts this definition. In fact, all embodiments of a "neutralizer" have these structural elements. *Id.* at col.3, ll.1-15, J.A. 94.

Such a construction also is supported by the prosecution history of the '568 Patent's parent '465 Patent. *See Biovail Corp. v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001) (considering prosecution history of parent patent in claim construction). The amended Claim 1 of the parent application contained the term "neutralizer," which was described as "having a housing, protractor, an angularly adjustable plate capable of supporting a foot" and "adapted to accommodate a single foot of the individual to determine the neutral angle for each foot of the individual separately." J.A. 74. This term was used consistently throughout the prosecution history. The inventor had the opportunity to indicate that the term "neutralizer" as it appears in the '568 Patent was somehow different from the term as it was used in the parent patent, but did not do so.

Of course, "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." *Phillips*, 415 F.3d at 1323. ProFoot argues that the '568 Patent's specification supports a broader construction of a "neutralizer" and that reading the term as having specific structural features improperly limits the claim language to the preferred embodiment. Pl.'s Br. 8, 11. ProFoot points to the Summary of the Invention, which describes "a device and method that measures and then corrects the pronation of the foot" and discusses the method of analyzing the ankle joint to achieve balance. *Id.* 8. It also argues that the Description of the Preferred Embodiments depicts only exemplary measuring devices as the

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introduction to the section specifies, pointing to the language in the patent that [f]uture and present alternatives and modifications are contemplated." *Id.* 9.

But claim terms should be read in the context of the *entire patent*. *Phillips*, 415 F.3d at 1313. And here, the '568 Patent as a whole makes it clear that a "neutralizer" is not simply a "balance measuring device." The device deals only with dynamic balance; it can accommodate a single foot and determine the angle necessary to place an ankle in a neutral position. '568 Patent col.2 II.3-19, J.A. 93; col.5 II.11-15, J.A. 95; Abstract, J.A. 89. Moreover, it is described as having a housing, a protractor, and an angularly adjustable plate capable of supporting the foot not only in the Description of the Preferred Embodiments, but also in the Abstract and in the parent patent application. *Id.* at Abstract, J.A. 89; J.A. 74. In the face of such intrinsic evidence, the boilerplate language cited by ProFoot carries little weight. *See Wireless Agents LLC v. Sony Ericsson Mobil Communs. AB*, 189 F. App'x 965, 967 (Fed. Cir. 2006); *IP Innovation, LLC v. Ecollege.com*, 156 F. App'x 317, 321-22 (Fed. Cir. 2005).

Compared to ProFoot's proposed construction, Merck's proposal comes closer to the description above, but does not mention "a housing" and adds the phrase "which are used to measure the angle of adjustment to achieve the neutral position of a specific individual's ankle." Def.'s Reply 1-2 (stating that "neutralizer" is "a device that includes an angularly adjustable plate and a protractor which are used to measure the angle of adjustment to achieve the neutral position of a specific individual's ankle"). Merck admits that "the definition previously expressed by the inventor is narrower than the definition [] proposed by Merck." *Id.* 13. However, it gives no explanation why the definition should not include "a housing," a structural element listed in the description of a "neutralizer" in the intrinsic evidence. '568 Patent Abstract, J.A. 89; J.A. 74. Next, incorporating the phrase "which are used to measure the angle of

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adjustment to achieve the neutral position of a specific individual's ankle" in the definition would result in repetitive language in Claim 1: "using a device that includes an angularly adjustable plate and a protractor which are used to measure the angle of adjustment to achieve the neutral position of a specific individual's ankle to determine the angle necessary to place the right ankle in a neutral position." See '568 Patent col.5 ll.14-15, J.A. 95. Hence, this phrase should not be included in the definition.

For these reasons, the Court will construe "neutralizer" to mean "a device that has a housing, a protractor, and an angularly adjustable plate capable of supporting the foot."

B. "Neutral position"

The Court next construes the term "neutral position." Merck proposes that "neutral position" used in Claim 1 means "a state or position in which the tendons by the individual's ankle are in a relaxed state or are working equally." Def.'s Reply 2. ProFoot counters that the term should be given its plain and ordinary meaning, which is "balanced position." Pl.'s Br. 5.

ProFoot's proposed construction suffers from several deficiencies. First, the '568 Patent's Summary of the Invention reveals that there are several types of balances and balanced positions. '568 Patent col.2 II.3-19, J.A. 93. But the invention concerns only a "dynamic" balance that is achieved by standing on one foot. *Id.* In fact, Claim 1 itself states that "neutral position" is determined when individual places one foot on the neutralizer and elevates another foot off of the neutralizer. *Id.* at col.5 II.11-13, col. 6 II.3-5, J.A. 95.

Next, "neutral position" corresponds to a specific ankle position or, to be precise, to a particular subtalar joint position, *i.e.*, the position between pronation and supination. Claim 1

A subtalar joint is a joint that allows a foot to move from the orientation where the big toe is over the smaller toes (called pronation) to the orientation where the smaller toes are over the big toe (called supination). See '568 Patent col.1 ll.12-15, J.A. 93 ("the present invention concerns a device and method that produces an insert or foot support that positions the ankle joint or sub taylor [sic: subtalar] joint in a

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itself states that there is a particular angle that is "necessary to place the right ankle in a neutral position." Id. at col.5 ll.14-15, J.A. 95 (emphasis added). Furthermore, the Background of Invention explains that "the present invention concerns a device and method that produces an insert or foot support that positions the ankle joint or sub taylor [sic: subtalar] joint in a relaxed position by correcting the pronation of the foot." Id. at col.1 ll.12-15, J.A. 93 (emphasis added). Likewise, the Summary of the Invention discloses that "[t]his invention provides a device and method that measures and then corrects pronation of the foot." Id. at col.1 ll.17-18, J.A. 93 (emphasis added). It further elaborates that "[u]nderstanding the demands of skiing specifically was the thrust behind the invention. . . . If the sub taylor [sic] joint is predisposed with nonfunctional tension, the ability to move freely will be jeopardized." *Id.* at col.1 ll.40-48, J.A. 93 (emphasis added). And, it also points out that "[t]o achieve the proper pronation of the sub taylor [sic] joint, how the foot is designed to support weight, and walk must be understood." Id. at col.1 ll.52-54, J.A. 93 (emphasis added). The discussion of the "dynamic" balance in the Summary of the Invention is also instructive: "[t]he present invention achieves this state by first analyzing the ankle joint to determine correct foot alignment." Id. col.2 ll.17-19, J.A. 93 (emphasis added).

Moreover, the prosecution history reveals the importance of the position of the subtalar joint. The '568 Patent specification is almost identical to the specification of its parent application, but it contains an important difference; in the '568 Patent specification, the term "sub taylor [sic] joint" was added to or replaced the phrase "ankle joint," indicating that the

relaxed position by correcting the pronation of the foot"); col.4 ll.21-27, J.A. 94 ("To achieve a neutral position, the operator visually examines the tendons by the ankle until they are in a relaxed state or are working equally. This commonly occurs with no more than two degrees of adjustment of pronation—with the big toe of the foot over the smaller toes However, supination, orientation with smaller toes over the big toe, may also occur.").

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inventor wished to describe the relevant joint with greater specificity. *Compare id.* at col.1 ll.14, 46, 52, J.A. 93, *with* U.S. Patent No. 6,564,465 col.1 ll.11, 44, 50, J.A. 9.

Merck's proposed definition ("a state or position in which the tendons by the individual's ankle are in a relaxed state or are working equally") comes from the Description of the Preferred Embodiments, which states that "neutral position" is achieved when "the tendons by the ankle . . . are in a relaxed state or are working equally." '568 Patent col.4 Il.21-23, J.A. 94. But the Patent clarifies that "[t]his commonly occurs with no more than two degrees of adjustment of pronation. . . . However, supination . . . may also occur." Id. at col.4 Il.23-27, J.A. 94 (emphasis added). The relaxed state thus comes from the lack of pronation or supination. Add to this the Summary of the Invention, which explains the cause of the tension (i.e., the unrelaxed state) in the system:

If the *sub taylor* [sic] *joint* is predisposed with nonfunctional tension, the ability to move freely will be jeopardized. The fine muscular movements of the foot and ankle dictate the degree of success in the rest of the biomechanical chain. This is, to a large extent, the *cause of tension* or an imbalanced interaction in the chain.

Id. at col.1 ll.46-51, J.A. 93 (emphasis added). Therefore, the language in the Description of the Preferred Embodiments that Merck uses for its construction provides further support for the notion that the "neutral position" corresponds to a subtalar joint position that is between pronation and supination. In contrast, Merck's definition draws from the single description of the embodiment and not from the totality of the intrinsic evidence.

Accordingly, the Court will construe the term "neutral position" to mean "a position in which subtalar joint is in the relaxed position due to the lack of pronation or supination."

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C. "Using the neutralizer to determine the angle necessary to place the <right or left> ankle in a neutral position"

The next phrase to be construed, "using the neutralizer to determine the angle necessary to place the <ri>right or left> ankle in a neutral position," appears in Claim 1 of the '568 Patent. Merck asserts that the correct interpretation of the phrase is "using neutralizer by: (1) visually examining and adjusting the individual's <right or left> ankle to neutral position, and (2) measuring the angular degree of pronation or supination when that ankle is in the neutral position." Def.'s Reply 2. ProFoot counters that this phrase should be given its plain and ordinary meaning, that the only term at issue after accepting the construction of "neutralizer" and "neutral position" is "angle necessary," and that the term "angle necessary" needs no independent construction. Pl.'s Br. 6.

Merck's construction seeks to limit the claims to the preferred embodiment. Its definition is based on the Description of the Preferred Embodiments, the only place in the patent where the visual examination is mentioned. '568 Patent col.4 Il.21-23, J.A. 94. There is no other indication in the patent that the use of a "neutralizer" must involve visual inspection. On the contrary, the '568 Patent cites U.S. Patent No. 5,979,067, which describes another method to determine neutral position of a subtalar joint—palpation of the talus head. U.S. Patent No. 5,979,067 col.1 Il.21-28.² This intrinsic evidence indicates that a person of ordinary skill in the art would recognize that visual inspection alone is not the only means to determine the neutral position of the ankle joint. *See Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231 (Fed. Cir. 2011) (stating that the prior art cited in a patent or the prosecution history constitutes intrinsic evidence).

Although the parties did not include this patent in the Joint Appendix, the Court may take judicial notice of published patents under Fed. R. Evid. 201(b) & (c). *See Pepitone v. Am. Standard, Inc.*, No. 92-1284, 1992 WL 336539, at *3, n.1 (Fed. Cir. Nov. 17, 1992).

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Applying the Court's definitions of "neutralizer" and "neutral position," the phrase at issue becomes "using a device that has a housing, a protractor, and an angularly adjustable plate capable of supporting the foot to determine the angle necessary to place the <right or left> ankle in a position in which subtalar joint is in the relaxed position due to the lack of pronation or supination." There is no need to define the words "angle necessary." The two words as they appear in the Patent are easily understood and do not require interpretation. In context, they mean the angle measured by the protractor after the angularly adjustable plate is turned to place the subtalar joint in the relaxed position. *See, e.g.*, '568 Patent, col.4 ll.21-29, 39-40, J.A. 94 (discussing adjusting the plate to achieve a "neutral position" and measuring the corresponding angle by the protractor).

D. "Providing an insert having an angle which represents the neutral state for the <right or left> ankle"

Merck next suggests that the phrase "providing an insert having an angle which represents the neutral state for the <right or left> ankle" used in Claim 1 should be interpreted as "providing an insert that reflects the measured angular degree of pronation or supination of the individual's <right or left> foot that establishes the neutral position." Def.'s Reply 2. ProFoot replies that the phrase does not require further construction beyond its plain and ordinary meaning. Pl.'s Br. 6.

This phrase uses the term "neutral state" instead of "neutral position." The Description of the Preferred Embodiments connects the two terms. It explains that the neutralizer's plate is angularly adjusted "to achieve a *neutral position*" and the corresponding angle is then transferred to the "bed," which is then "placed inside a piece of sports equipment such as ski boot" to hold the foot "at the angle which is the *neutral state* for the ankle." '568 Patent col.4 II.4-58, J.A. 94

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(emphasis added). Thus, the ankle is at the same angle on the neutralizer's plate and on the "bed," and, hence, "neutral state" and "neutral position" signify the same position of the ankle.

Therefore, the Court replaces the term "neutral state" with the definition of "neutral position," and the phrase "providing an insert having an angle which represents the neutral state for the <right or left> ankle" becomes "providing an insert having an angle, which represents the position in which the subtalar joint is in the relaxed position due to the lack of pronation or supination, for the <right or left> ankle," which is similar to the Merck's construction. This phrase is easily understood. Again, the Court agrees with ProFoot that the term needs no further construction.

E. "Predetermined inserts"

Before construing the last disputed term of the independent Claim 1 ("creating a <right or left> foot insert"), the Court must first examine the term "predetermined inserts" that appears in dependent Claim 3. Merck argues that the term means "inserts that are pre-made with the previously measured angle that establishes the neutral position for the individual's <left or right> foot." Def.'s Reply 3. ProFoot again counters that the term needs no further construction beyond its plain and ordinary meaning. Pl.'s Br. 6.

The key concept in the Merck's construction is that the fabrication of inserts "is based on individualized measurement of the individual's foot and ankle." Def.'s Reply 10. But "[t]hose measurements can be stored and used to create an individualized insert at any time," so "fabrication of inserts can occur at any time." *Id.* Although it is certainly imaginable that one can save an individual's measurements to use it later to manufacture an insert, there is nothing in the intrinsic evidence to suggest this route. Instead, the '568 Patent's specification describes inserts that are pre-made without using a particular individual's measurements: "the inserts []

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may be pre-made with a range of predetermined angles. For example, insert [] may have an angle that ranges from ½ a degree to 3 degrees . . . in ½ degree increments. This reduces the turn-around time to complete the process." '568 Patent col.4 ll.61-65, J.A. 94. Merck's proposed definition thus ignores important intrinsic evidence. Furthermore, Claim 3 itself states that the "insert is provided to a user by selecting said insert from a *plurality* of predetermined inserts." *Id.* at col.6 ll.12-14, J.A. 95 (emphasis added). Under Merck's definition, the insert would have to be chosen from the plurality of the *same* inserts made using individual's measurement. This would be a nonsensical result.

Overall, the Court agrees with ProFoot that "predetermined inserts" is an easily understandable term and does not require further construction beyond its plain and ordinary meaning.

F. "Creating a <right or left> foot insert"

Finally, the term "creating a <right or left> foot insert" appears in Claim 1 of the '568 Patent. Merck reads this term to mean "fabricating a foot insert based on an operator's measurements of the individual's <right or left> foot." Def.'s Reply 2. ProFoot replies that the term needs no further construction beyond its plain and ordinary meaning or, in alternative, that "creating" should be construed as "determining a right or left insert." Pl.'s Br. 6.

Merck's construction hinges on the idea that the insert is made using individualized measurements. Def.'s Reply 10. Specifically, Merck points out that in Claim 1 "the three substeps that follow the term[] . . . indicate that inserts are to be fabricated to have an angle that represents the neutral position." Def.'s Opening Claim Construction Br. 19. Merck further refers to the specification, which discusses the importance of measuring each foot independently,

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evaluating pronation, and positioning the ankle in a relaxed position by correcting the pronation of the foot. *Id.* 20.

As an initial matter, the Court agrees that the phrase "creating a <right or left> foot insert" encompasses fabricating an insert based on the individual's measurements. But that is not all that the term encompasses. Dependent Claim 3 states that the insert can be "provided to a user by selecting said insert from a plurality of predetermined inserts." '568 Patent col.6 Il.12-14, J.A. 95. This means that "creating" must also include a scenario where a "predetermined insert" is provided to a user. This interpretation is further supported by the patent's specification, which describes both, making an insert using individual's measurements and pre-making inserts "with a range of predetermined angles." *Id.* at col.4 Il.28-55, 61-64, J.A. 94.

The plain and ordinary meaning of "create" (e.g., "to cause to come into being") encompasses both scenarios and is consistent with the entirety of the '568 Patent, not just the excerpts selected by Merck. See Pl.'s Br. 18. (suggesting that "create" broadly means "to cause to come into being"). Therefore, the Court agrees with ProFoot that the term does not require construction.

IV. Terms as Construed

#	<u>Term</u>	<u>Definition</u>
I	"Neutralizer"	"A device that has a housing, a protractor, and an angularly adjustable plate capable of supporting the foot"
II	"Neutral position"	"A position in which subtalar joint is in the relaxed position due to the lack of pronation or supination"
III	"Using the neutralizer to determine the angle necessary to place the <right left="" or=""> ankle in a neutral position"</right>	No construction required once the definitions of the terms "neutralizer" and "neutral position" are applied.

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IV	"Providing an insert having an angle which represents the neutral state for the <right left="" or=""> ankle"</right>	No construction required once "neutral state" is replaced with the definition of the "neutral position."
V	"Predetermined inserts"	No construction required.
VI	"Creating a <right left="" or=""> foot insert"</right>	No construction required.

For the foregoing reasons, the six disputed claim terms are construed as set forth in this Memorandum Opinion and Order.

IT IS SO ORDERED.

ENTERED 6/17/15

John Z. Lee

United States District Judge

Case: 1:11-cv-09004 Document #: 138 Filed: 09/23/15 Page 1 of 3 PageID #:1790

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

PROFOOT INC.,

Plaintiff,

v.

Civil No. 1:11-cv-9004

MERCK & CO., INC,

JURY TRIAL DEMANDED
The Honorable John Z. Lee

Defendant.

STIPULATED FINAL JUDGMENT OF NON-INFRINGEMENT

WHEREAS, this is a patent infringement action brought by ProFoot, Inc., as successor in interest to Eric Ward ("ProFoot" or "Plaintiff") against Bayer HealthCare LLC, a wholly owned subsidiary of Bayer AG and the successor in interest to the Dr. Scholl's business of Merck & Co., Inc. (hereinafter, "Bayer" or "Defendant");

WHEREAS, this Court has jurisdiction over the claims and counterclaims in this action pursuant to 28 U.S.C. §§ 1331, 1338, and 2201-2202;

WHEREAS, ProFoot has claimed that Defendant has infringed claims 1 and 3 of its United States Patent No. 6,845,568 ("the '568 patent" or the "Asserted Patent");

WHEREAS, Defendant contends that it does not infringe the Asserted Patent:

WHEREAS, on June 17, 2015, the Court issued a Memorandum Opinion and Order on claim construction in which it: (a) construed the term "Neutralizer" to mean "a device that has a housing, a protractor, and an angularly adjustable plate capable of supporting the foot," and (b) construed the term "Neutral Position" to mean "a position in which subtalar joint is in the relaxed position due to the lack of pronation or supination." (D.I. 132);

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WHEREAS, in the interests of efficiency, judicial economy, and to avoid unnecessary

fees and costs to the parties, ProFoot concedes, without prejudice to an appeal, its rights to a

finding of infringement of the Asserted Patent due to the Court's claim construction;

WHEREAS, ProFoot and Bayer stipulate and agree to entry of final judgment of non-

infringement of Plaintiff's '568 patent;

WHEREAS, Plaintiff has granted Defendant an irrevocable Covenant-Not-To-Sue and

Release under the '568 patent, contingent only upon the final judgment entered hereby being

fully affirmed or otherwise becoming non-appealable.

IT IS HEREBY ORDERED that the parties' Stipulated Final Judgment of Non-

Infringement is GRANTED. This judgment is subject to the same right of appeal that ProFoot

would have had in the event a final judgment of non-infringement had been entered following

either a dispositive ruling by the Court or a jury verdict;

IT IS FURTHER ORDERED that Defendant's affirmative defenses and counterclaims

are dismissed without prejudice to Defendant's right to reassert its defenses and counterclaims in

the event of remand after appeal;

IT IS FURTHER ORDERED that the deadlines for filing a request for attorneys' fees or

costs pursuant to Federal Rule of Civil Procedure 54(d)(2) in this action are adjourned until after

the appellate process is complete and the judgment of non-infringement affirmed, at which time,

the parties shall meet and confer and promptly submit a proposed briefing schedule on the issue

after issuance of the mandate; and

IT IS FURTHER ORDERED that all remaining deadlines set forth in the Court's Minute

Entry of June 25, 2015 (Dkt. No. 133) are hereby vacated.

So Ordered this _____ day of _______, 2015

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Appx20

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Judge John Z. Lee

Jointly Submitted this September 23, 2015

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UNITED STATES DISTRICT COURT FOR THE Northern District of Illinois – CM/ECF LIVE, Ver 6,1 Eastern Division

Merck & Co., Inc., et al.

Plaintiff,

v. Case No.: 1:11-cv-09004

Honorable John Z. Lee

Merck & Co., Inc., et al.

Defendant.

NOTIFICATION OF DOCKET ENTRY

This docket entry was made by the Clerk on Friday, September 25, 2015:

MINUTE entry before the Honorable John Z. Lee: The parties have entered a stipulated final judgment of non-infringement. [138] The parties' stipulation is hereby approved, and final judgment is entered against Plaintiff in accordance with the terms of the stipulated final judgment. Civil case terminated. Mailed notice(ca,)

ATTENTION: This notice is being sent pursuant to Rule 77(d) of the Federal Rules of Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was generated by CM/ECF, the automated docketing system used to maintain the civil and criminal dockets of this District. If a minute order or other document is enclosed, please refer to it for additional information.

For scheduled events, motion practices, recent opinions and other information, visit our web site at www.ilnd.uscourts.gov.

Case: 16-1216 Document: 23 Page: 60 Filed: 02/19/2016



(12) United States Patent Ward

US 6,845,568 B2 (10) Patent No.: (45) Date of Patent: Jan. 25, 2005

(54) HIGH PERFORMANCE FOOT BED FOR SPORTS EQUIPMENT

Inventor: Eric G. Ward, P.O. Box 2574, Aspen, (76)CO (US) 81612

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

(21) Appl. No.: 10/389,435

(22)Filed: Mar. 14, 2003

Prior Publication Data (65)

US 2003/0213138 A1 Nov. 20, 2003

Related U.S. Application Data

(63)	Continuation-in-part of application No. 09/667,998, filed on
` ′	Sep. 22, 2000, now Pat. No. 6,564,465.

(51)	Int. Cl. ⁷	A61B 5/103
(52)	U.S. Cl	33/515; 33/3 R; 600/592;
		12/1 G: 12/142 D

(58) Field of Search 33/2 R, 3 R, 6, 3 A, 3 C, 3 B; 600/592; 12/1 R, 1 G, 142 R

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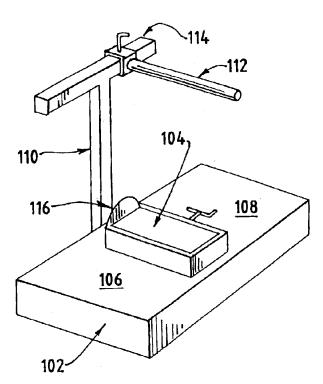
^{*} cited by examiner

Primary Examiner—Christopher W. Fulton (74) Attorney, Agent, or Firm-Niro, Scavone, Haller & Niro

(57) **ABSTRACT**

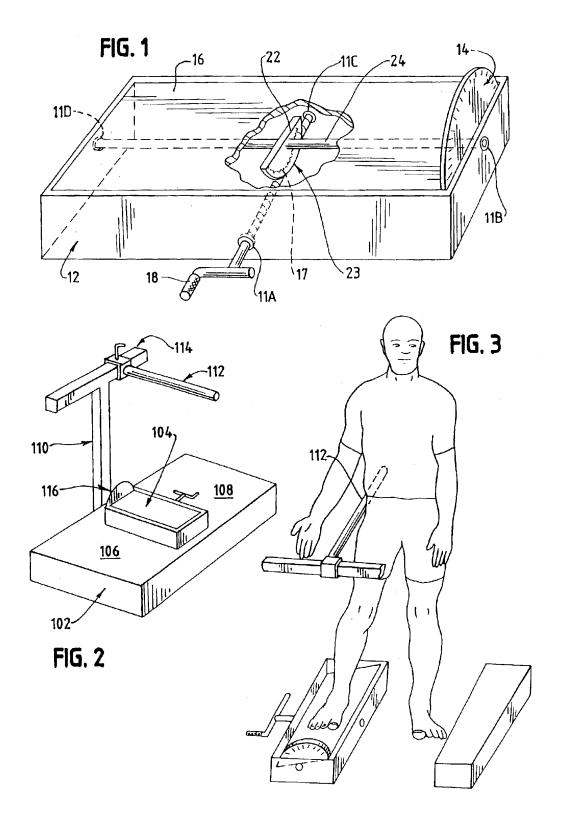
A system for creating at least one foot insert for an individual using a neutralizer 10, a levelor 40, and a sled 60. The neutralizer has a housing, protractor, and an angularly adjustable plate capable of supporting the foot. The neutralizer is adapted to accommodate a single foot of the individual to determine the neutral angle for each foot individually. The levelor is positionable on the neutralizer and has a plurality of adjustable arms to transfer the neutral angle from the neutralizer to the levelor. The levelor is also mountable to the sled with the adjustable arms being adapted to engage an insert for transferring the neutral angle to the insert.

3 Claims, 3 Drawing Sheets



U.S. Patent Jan. 25, 2005 Sheet 1 of 3

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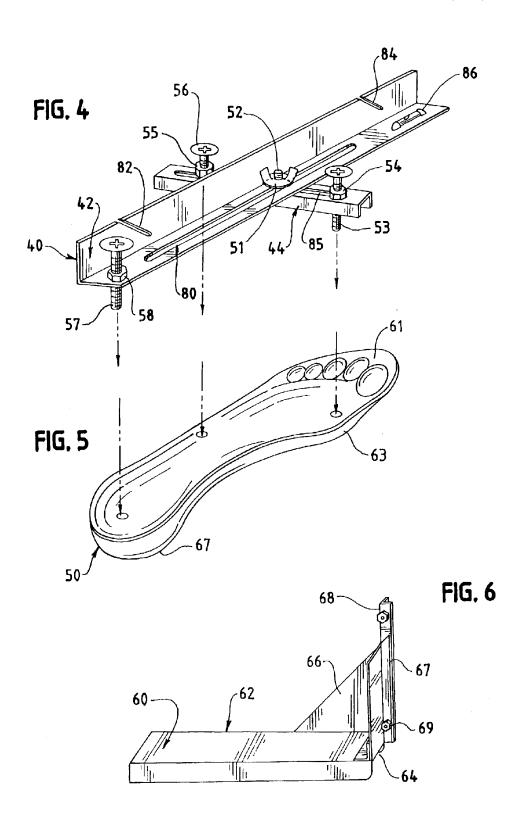


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Sheet 2 of 3

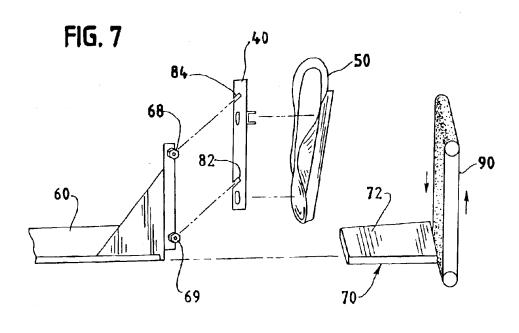
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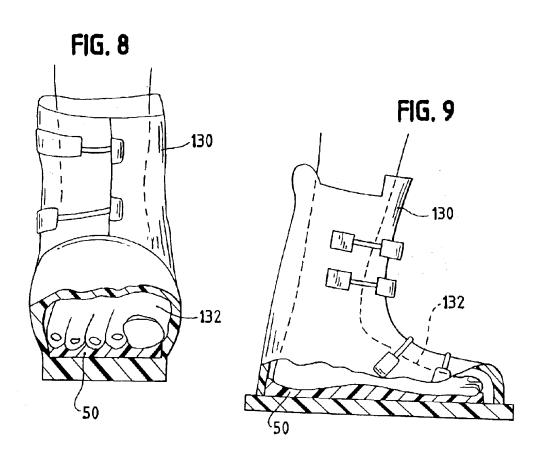


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Sheet 3 of 3

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HIGH PERFORMANCE FOOT BED FOR SPORTS EQUIPMENT

This application is a CIP of U.S. application Ser. No. 09/667,998 filed Sep. 22, 2000, now U.S. Pat. No. 6,564, 5 465.

BACKGROUND OF THE INVENTION

The present invention relates to a device and method for forming an athletic foot support that may be used in such 10 equipment as, among other things, ski boots, skates, bike shoes and the like. More specifically, the present invention concerns a device and method that produces an insert or foot support that positions the ankle joint or sub taylor joint in a relaxed position by correcting the pronation of the foot. 15

SUMMARY OF THE INVENTION

This invention provides a device and method that measures and then corrects the pronation of the foot, a condition where the foot collapses to the medial or inside of the foot, $_{20}$ and how this affects athletic ability. The degree of pronation is evaluated for each foot independently. The end result provides an equal amount of pronation to occur in each foot by building a corrective mold of the foot, or a "canted footbed". Being that most individual's feet have individual 25 needs, it is critical to evaluate each foot separately. This is important to many athletic activities that demand the athlete to move symmetrically—for instance, skiing, skating, and any other laterally-oriented sport. The term "canted footbed" like a house, provides a solid level object for the house to sit 30 upon. The foot bed is the foundation for the muscularskeletal system to sit upon and work most efficiently since the foot is a complex joint. Not only does it support enormous amounts of weight, but it is the primary joint for balancing. The present invention is a process and device that 35 takes both of these factors into consideration. The foot must be able to support the weight of the body plus the added weight of G forces, especially in skiing. While supporting large loads, it must also be able to make fine-tuning movements while skiing. Understanding the demands of skiing $_{40}$ specifically was the thrust behind the invention. The physics of the sport require that the skier balance on top of a frictionless surface while moving dynamically from one foot to the other. Symmetric movement is important in the creation of a seamless move from one side to the other with 45 rhythmic flow. If the sub taylor joint is predisposed with nonfunctional tension, the ability to move freely will be jeopardized. The fine muscular movements of the foot and ankle dictate the degree of success in the rest of the biomechanical chain. This is, to a large extent, the cause of $_{50}$ tension or an imbalanced interaction in the chain.

To achieve the proper pronation of the sub taylor joint, how the foot is designed to support weight, and walk must be understood, or what is commonly referred to as a dynamic gate. The phases of the dynamic gate are heel 55 strike, mid range, and toe off.

In the heel strike, the calcaneus hits the ground usually to the lateral side of the foot. Then the hips move forward and the weight moves to the outer three metatarsals to support lateral balance. This is known as the midrange. Then, the foot naturally pronates to one degree or another to allow the weight to move to the medial side of the foot or the two strong toes. Then, as the hips pass in front of the foot, the large strong toes will push off. This is the understanding of the dynamics of the foot in a stride.

In skiing, biking, skating, etc... because the equipment limits the range of motion, there is no stride, there is only

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lateral movement—basically, stuck in the midrange mode. It is however a dynamic stance, because the foot moves laterally to create balance while the body is in motion. This is the difference between what the present invention achieves and what many others do in this field. All other alignment processes implement a two-footed stance to determine the position of neutrality. This is done by aligning the center of the knee in relation to the center of support. This is done while standing on two feet or in a static state. If a person is standing on two feet, you then have to look at the base of support as being a six piece balancing system. In this situation, the person may be maintaining balance equally in all six quadrants or in one of the six quadrants and using two others to maintain a steady or "static" balance.

If you reduce the base of support to only one foot, you have a three-sided base which needs to articulate to maintain balance or balance dynamically. The present invention achieves this state by first analyzing the ankle joint to determine correct foot alignment. The balance analyser and the foot level control quality and assure accuracy of the foot foundation used in the insert. Typically, the optimal outcome should be to limit the amount of pronation in the ankle to approximately two degrees. The application of this type of process to foot beds will increase the amount of relatedness in the foot and ankle joint. The subsequent outcome will be more athleticism in the user. The position of the foot will provide an ability for the user to move the foot laterally and with a great deal of agility.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features which are characteristic of the present invention are set forth in the appended claims. The invention itself, however, together with further objects and attendant advantages, will be best understood by reference to the following description taken in connection with the accompanying drawings in which:

- FIG. 1 shows a perspective view of one embodiment of a foot neutralizer used with the present invention;
- FIG. 2 shows a perspective view of an alternate embodiment of a foot neutralizer which may be used with the present invention;
- FIG. 3 illustrates how the foot neutralizer shown in FIG. 1 is used to take a pronation measurement;
- FIG. 4 is a perspective view of a leveler used with the present invention;
- FIG. 5 is a perspective view of an insert used with the present invention;
- FIG. 6 is a perspective view of a jig used with the present invention;
- FIG. 7 is an exploded perspective view illustrating various manufacturing steps used with one embodiment of the invention;
- FIG. 8 is a front view showing an insert located in a ski boot; and
 - FIG. 9 is a side view showing an insert in a ski boot.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Set forth below is a description of what is currently believed to be the preferred embodiment or best example of the invention claimed. Future and present alternatives and modifications to the preferred embodiment are contemplated. Any alternates or modifications in which insubstantial changes in function, purpose, structure or result are intended to be covered by the claims of this patent.

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The present invention includes a number of components such as a foot neutralizer 10 as shown in FIG. 1, a leveler 40 as shown in FIG. 4, a foot bed 50 as shown in FIG. 5, a sled 60 as shown in FIG. 6, and a sander 70 as shown in FIG. 7. Neutralizer 10 includes a housing 12, protractor 14, an angularly adjustable plate 16, crank 18 with threaded rod 19 having threads 23 that coact with threads 21 on support 22, and rod 24. Bearings 11A, 11B, 11C and 11D may also be provided for ease of operation.

FIG. 2 shows an alternate embodiment of a foot neutralizer 100. It includes a housing 102, angularly adjustable plate 104, foot rests 106 and 108, upright support bar 110, and a positionable horizontal bar 112 that adjustably slides along bar 114 of support 110. Also included is protractor 116

Leveler 40 includes arm 42, which may be made from a piece of angle iron, and arm 44, which may be made from a unshaped channel. As shown in FIG. 4, arms 42 and 44 are generally disposed in a perpendicular relationship. Included on arm 42 are slanted notches 82 and 84 and extended groove 80. A two-way bubble indicator 86 is located on one end of arm 42. Indicator 86 may be comprised of tubing that encloses liquid and an air bubble.

Also provided on leveler 40 are a number of coacting fasteners 51–58. Fastener 52 may be a wing nut which coacts with fastener 51 which is located inside groove 80. This arrangement allows the overall length of the leveler to be adjusted to accommodate various foot sizes. Fasteners 53–56 are used to adjust the width of the leveler by being adjustable within groove 85. These fasteners along with fasteners 57 and 58 are also used to level the leveler as will be described in further detail below.

Also included with the present invention is a composite foot bed 50. It consists of a foot blank 51 which is molded to conform to the shape of the user's foot. A posting foam 53 is used as the base of the foot bed composite.

A sled 60 is also used with the present invention. It includes a base 62 defining a channel 64. Also included is upright post 67 which is supported by bracket 66.

Locking posts **68** and **69** are also provided. The locking posts function to connect the leveler to the sled. Locking posts **68** and **69** may be coacting fasteners or other clamping and locking devices.

A table **70** is also used which is adjacently located near a vertical sander. Table **70** includes a guide **72** which is sized to fit within channel **64** of sled **60**. Guide **72** and channel **64** are sized within a close tolerance so as to maintain a straight line as sled **60** moves along guide **72** as will be described in more detail below.

In use, a mold is first made for each foot of the individual. This may be done by a silicon bean bag on which a foot is placed. Air is then vacuumed out of the bag so that the shape of the impression is maintained. A plaster mold is made of the impression and then a plastic mold is made over the plaster mold to form foot blank 61 of composite foot bed 50. This is done by trimming blank 61 and attaching it to posting foam 63 by adhesives. As shown in FIG. 5, when this process is finished, foot bed 60 should consist of a foot blank 61 that conforms to a user's foot which has been attached to a base 63 made of posting foam, which has a flat surface 67.

Next, leveler 40 is positioned on the foot bed. This is done by placing fastener 57 near what would be the heel portion of the foot bed at the center line. Fasteners 56 and 53 are then placed at the outer edges of bed 50 near the toe line. For 65 reference purposes, to relocate the leveler on bed 50 for use in later finishing steps, reference marks may be made on bed

50 by a common marker. With the leveler 40 at rest on bed 50, the lengths of fasteners 53, 56 and 57 are adjusted to level leveler 40 on bed 50 through the use of bubble level 86.

To determine an individual's neutral ankle position, foot neutralizer 10 or 100 is used. To determine a neutral position, one foot at a time is measured, while maintaining an individual in the same upright, relaxed stance. To do this, for an individual's left foot, the person stands on foot neutralizer 100. The left foot is placed on plate 104 which is in a level position and the right foot is placed on rest 108. The individual then stands upright in a relaxed position and may use bar 114 for support. Wand or bar 112 is located next to the person's hip which acts as reference point for maintaining this position.

The heel of the foot is placed on the center line which is defined by rod 24. Crank 18 is then operated by rotation which causes threads 21 and 23 to coact thereby resulting in plate 16 being angularly adjusted. Protractor 14 indicates the amount of adjustment undertaken. The same type of adjustment system is also used with the neutralizer shown in FIG.

To achieve a neutral position, the operator visually examines the tendons by the ankle until they are in a relaxed state or are working equally. This commonly occurs with no more than two degrees of adjustment of pronation—with the big toe of the foot over the smaller toes as shown in FIG. 3. However, supination, orientation with smaller toes over the big toe, may also occur.

Next the adjustment plate is left at the angular orientation selected and may be locked in place. Leveler 40 is then placed on plate 16 or 104 in approximately the same location as was the foot. The lengths of fasteners 53, 56 and 57 are then adjusted to level leveler 40 by observing bubble levels 86. It should be noted that fasteners 54, 55 and 58 may be a double nut arrangement which assists in maintaining the desired location and length of the fasteners.

Next, leveler 40 is placed on foot bed 50 in the same position in which it was originally adjusted to level. Bed 50 and leveler 40 are then secured together by masking tape or other suitable means. Through this process, the angle of plate 16 or 104 as measured by the protractor will be transferred to bed 50.

As shown in FIG. 7, leveler 40 is mounted to sled 60. This is done by inserting grooves 82 and 84 onto locking knobs or posts 68 and 69 which are sized to fit inside of the grooves. Sander 90 is then activated and is used to remove the flat surface 67 of bed 50.

To do this sled 60 is mounted on table 70 by placing guide 72 inside channel 64. This allows surface 67 of bed 50 to be urged against sander 90 which removes the foam of bed 50 to reproduce the same angle as that of plate 16 or 104. Once the sander has removed a sufficient amount of material along the entire length and width of bed 50, the process is completed. To perform the process for the other foot, the exact some procedure is used.

As shown in FIGS. 8 and 9, bed 50 is placed inside a piece of sports equipment such as ski boot 130. As shown, bed 50 holds foot 132 at the angle which is the neutral state for the ankle. Of course, as mentioned above, bed or insert 50 may be used in other sports equipment as well.

In addition, the inserts **50** may be pre-made with a range of predetermined angles. For example, insert **50** may have an angle that ranges from ½ a degree to 3 degrees and be pre-made in ½ degree increments. This reduces the turnaround time to complete the process.

It should be understood that various changes and modifications to the preferred embodiment described would be

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apparent to those skilled in the art. Changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is, therefore, intended that such changes and modifications be covered by the following 5 claims.

What is claimed is:

1. A method of fitting an individual with right and left foot inserts which place the ankles of the individual in a neutral position comprising the steps of:

for creating a right foot insert, having the individual place the right foot on a neutralizer while elevating the left foot off of the neutralizer;

using the neutralizer to determine the angle necessary to place the right ankle in a neutral position;

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providing an insert having an angle which represents the neutral state for the right ankle;

for creating a left foot insert, having the individual place the left foot on a neutralizer while elevating the right foot off of the neutralizer;

using the neutralizer to determine the angle necessary to place the left ankle in a neutral position; and

providing an insert having an angle which represents the neutral state for the left ankle.

2. The method of claim 1 further comprising the step of making said insert conform to the foot of the user.

3. The method of claim 1 wherein said insert is provided to a user by selecting said insert from a plurality of predetermined inserts.

* * * * :

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). This brief contains 6,657 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

The brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally-spaced typeface using Microsoft Word 2010 in 14-point Times New Roman type.

/s/ William L. Niro
William L. Niro

CERTIFICATE OF SERVICE

I, Rose E. Olejniczak, being duly sworn according to law and being over the age of 18, upon my oath deposes and states that:

Counsel Press was retained by Niro Law Group, LLC, Attorneys for Plaintiff-Appellant, ProFoot, Inc. to print this document. I am an employee of Counsel Press.

On February 19, 2016, Niro Law Group, LLC authorized me to electronically file the foregoing Brief of Plaintiff-Appellant ProFoot, Inc. with the Clerk of the Federal Circuit using the CM/ECF System, which will serve e-mail notice of such filing on the following attorneys:

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